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U. S. TRADEMARK OFFICE  
Applicants: Rabbani et al

Serial No. 09/896,897 Group Art Unit: Not yet determined

Filed: June 30, 2001 Examiner: Not yet determined

Title: NOVEL COMPOSITIONS AND PROCESSES FOR ANALYTE DETECTION,  
QUANTIFICATION AND AMPLIFICATION

TRANSMITTAL  
INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

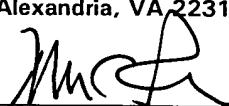
Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

**EXPRESS MAIL CERTIFICATE**

"Express Mail" Label No.: EL634886121US  
Deposit Date: January 7, 2004

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Ronald C. Fedus  
Reg. No. 32,567

JAN 7, 2004  
Date

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Charge the fee to Deposit Account No. 05-1135, Order No. **Enz-60**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. [ ] A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:

- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
- b. the attached petition requesting consideration of this Information Disclosure Statement; and
- c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.

8. [ ] A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:

- a. [ ] 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
- b. [ ] 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
- c. [ ] The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.

9. [ ] I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

[ ] I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Rabbani et al  
Serial No.: 09/896,897  
Filed: June 30, 2001  
Page 8 [Information Disclosure Statement  
– January 7, 2004]

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Ronald C. Fedus  
Registration No. 32,567  
Natalie Bogdanos  
Registration No. 51,480  
Attorneys for Applicants

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Tel. (212) 583-0100

10. [ ] A check in the amount of \$180.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. **Enz-60**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

By:   
Ronald C. Fedus  
Registration No. 32,567

Dated: January 7, 2004

Mailing Address:

ENZO LIFE SCIENCES, INC.  
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**Enz-60**

1. [ ] For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. [ ] For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. [ ] Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior [ ] Divisional or [ ] Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_.
4. [ ] No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
  - [ ] 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
  - [ ] 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
  - [ ] 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. [ ] No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. [x] A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
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527 Madison Avenue, 9<sup>th</sup> Floor  
New York, New York 10022  
January 7, 2004

**FILED VIA EXPRESS MAIL**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§1.56 & 1.971.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.971.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following fifty-four (54) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

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Rabbani et al  
Serial No.: 09/896,897  
Filed: June 30, 2001  
Page 2 [Information Disclosure Statement  
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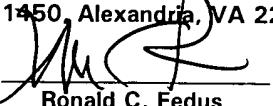
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Rabbani et al

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Page 3 [Information Disclosure Statement  
- January 7, 2004]

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1. *Adams, et al., Complementary DNA sequencing: expressed sequence tags and human genome project," Science 252:1651-1656 (1991) [Exhibit 1];*

2. Adams, et al., U.S. Patent No. 5,641,658, filed Aug. 3, 1994 [Exhibit 2];

3. Afanassiev, et al., "Preparation of DNA and protein micro arrays on glass slides coated with an agarose film," Nucl. Acids Res. 28:e66 (2000) [Exhibit 3];

4. Antopolksky, M., et al., "Solid-phase synthesis of peptide-oligonucleotide conjugates on new solid supports," Helv. Chim Acta 82:2130-2140 (1999) [Exhibit 4];

5. Arar, K., et al., "Synthesis of oligonucleotide-peptide conjugates containing a KDEL signal sequence," Tetrahedron Letters 34:8087-8090 (1993) [Exhibit 5];

6. Arenkov, P., et al., "Protein Microchips: Use for Immunoassay and Enzymatic Reactions," Analytical Biochemistry 278:123-131 (2000) [Exhibit 6];

7. Bazin, et al., *Innovation and Perspectives in solid Phase Synthesis & Recombinatorial Libraries*, R. Epton (Ed.), Mayflower Scientific Ltd., Birmingham, UK (1999) [Exhibit 7];

8. Bergmann, F., et al., "Solid phase synthesis of directly linked peptide-oligodeoxynucleotide hybrids using standard synthesis protocols," Tetrahedron Letters 36:1839-1842 (1995) [Exhibit 8];

9. Brenner, S., et al., "Encoded Combinatorial Chemistry," Proc. Natl. Acad. Sci. USA 89:5381-5383 (1992) [Exhibit 9];

10. Cho, R.J., et al., "A Genome-Wide Transcriptional Analysis of the Mitotic Cell Cycle," Mol. Cell 2:65-73 (1998) [Exhibit 10];

11. Cook, et al., U.S. Patent No. 6,204,326, filed Aug. 7, 1998 [Exhibit 11];

12. De La Torre, B.G., et al., "Stepwise solid-phase synthesis of oligonucleotide-peptide hybrids," Tetrahedron Letters 35:2733-2736 (1994) [Exhibit 12];

13. De La Torre, B.G., et al., "Synthesis and binding properties of oligonucleotides carrying nuclear localization sequences," Bioconjugate Chemistry 10:1005-1012 (1999) [Exhibit 13];

14. De Wildt, R.M., et al., "Antibody arrays for high-throughput screening of antibody-antigen interactions," Nature Biotechnology 18:989-994 (2000) [Exhibit 14];
15. Ede, N.J., et al., "Routine Preparation of Thiol Oligonucleotides: Application to the Synthesis of Oligonucleotide-Peptide Hybrids," Bioconjugate Chemistry 5:373-378 (1994) [Exhibit 15];
16. Edwards, J.B.D.M., et al., "Oligodeoxyribonucleotide ligation to single-stranded cDNAs: a new tool for cloning 5' ends of mRNAs and for constructing cDNA libraries by in vitro amplification," Nucleic Acids Research 19:5227-5232 (1991) [Exhibit 16];
17. Endege, W.O., et al., "Representative cDNA Libraries and Their Utility in Gene Expression Profiling," Biotechniques 26:542-550 (1999) [Exhibit 17];
18. Engelhardt, et al., U.S. Patent No. 5,241,060, filed June 4, 1990 [Exhibit 18];
19. Eritja, R., et al., "Synthesis of defined peptide-oligonucleotide hybrids containing a nuclear transport signal sequence," Tetrahedron 47:4113-4120 (1991) [Exhibit 19];
20. Fuller, C.W., U.S. Patent No. 5,432,065, filed Mar. 30, 1993 [Exhibit 20];
21. Gentalen, E., et al., "A novel method for determining linkage between DNA sequences: hybridization to paired probe arrays," Nucleic Acids Research 27:1485-1491 (1999) [Exhibit 21];
22. Haab, B.B., et al., "Protein microarrays for highly parallel detection and quantitation of specific proteins and antibodies in complex solutions," Genome Biology 2:1-13 (2001) [Exhibit 22];
23. Heller, et al., U.S. Patent No. 5,605,662, filed Nov. 1, 1993 [Exhibit 23];
24. Hirschhorn, J.N., et al., "SBE-TAGS: An array-based method for efficient single-nucleotide polymorphism genotyping," Proc. Natl. Acad. Sci. USA 97:12164-12169 (2000) [Exhibit 24];

25. Kwoh, D.Y., et al., "Transcription-based amplification system and detection of amplified human immunodeficiency virus type 1 with a bead-based sandwich hybridization format," Proc. Nat. Acad. Sci. USA 86:1173-1177 (1989) [Exhibit 25];
26. Koonin, E.V., et al., "The phylogeny of RNA-dependent RNA polymerase of positive-strand RNA viruses," J. Gen. Virol. 72:2197-2206 (1991) [Exhibit 26];
27. Lakobashvill, R., et al., "Low temperature cycled PCR protocol for Klenow fragment of DNA polymerase I in the presence of praline," Nucleic Acids Research 27:1566-1568 (1999) [Exhibit 27];
28. Lockhart, D.J., et al., "Expression monitoring by hybridization to high-density oligonucleotide arrays," Nature Biotechnology 14:1675-1680 (1996) [Exhibit 28];
29. Lohse, et al., International Patent Application No. WO 00/32823, filed December 2, 1999 [Exhibit 29];
30. Lueking, A., et al., "Protein microarrays for gene expression and antibody screening," Anal. Biochem. 270:103-111 (1999) [Exhibit 30];
31. Matz, M., et al., "Amplification of cDNA ends based on template-switching effect and step-out PCR," Nucleic Acids Research 27:1558-1560 (1999) [Exhibit 31];
32. Mendoza, L.G., et al., "High-Throughput Microarray-Based Enzyme-Linked Immunosorbent Assay (ELISA)," Biotechniques 27:778-788 (1999) [Exhibit 32];
33. Needels, M.C., et al., "Generation and screening of an oligonucleotide-encoded synthetic peptide library," Proc. Natl. Acad. Sci. USA 90:10700-10704 (1993) [Exhibit 33];
34. Okamoto, T., et al., "Microarray fabrication with covalent attachment of DNA using Bubble Jet technology," Nature Biotechnology 18:438-441 (2000) [Exhibit 34];
35. Pastinen, T., et al., "A System for Specific, High-throughput Genotyping by Allele-specific Primer Extension on Microarrays," Genome Research 10:1031-1042 (2000) [Exhibit 35];

36. Pergolizzi, et al., U.S. Patent Application No. 08/479,995, filed June 7, 1995 based on priority U.S. Patent Application No. 06/491,929, filed May 5, 1983; the specification subsequently published in European Patent EP 0 611 828, filed May 4, 1984 [Exhibit 36];
37. Perou, C.M., et al., "Distinctive gene expression patterns in human mammary epithelial cells and breast cancers," Proc. Nat. Acad. Sci. USA 96:9212-9217 (1999) [Exhibit 37];
38. Pirrung, et al., U.S. Patent No. 5,143,854, filed Mar. 7, 1990 [Exhibit 38];
39. Rabbani, et al., U.S. Patent Application No. 08/574,443, filed Dec. 15, 1995, abandoned in favor of U.S. Patent Application No. 08/978,632, filed Nov. 25, 1997; the specification subsequently published in divisional U.S. Patent Application No. 2003-0104620, published June 5, 2003 [Exhibit 39];
40. Rabbani, et al., U.S. Patent Application No. 09/104,067, filed June 24, 1998, the specification subsequently published in divisional U.S. Patent Application No. 2003-0104460, published June 5, 2003 [Exhibit 40];
41. Robles, J., et al., "Towards nucleopeptides containing any trifunctional amino acid," Tetrahedron 55:13251-13264 (1999) [Exhibit 41];
42. Spellman, et al., "Comprehensive identification of cell cycle-regulated genes of the yeast *Saccharomyces cerevisiae* by microarray hybridization," Mol. Biol. Cell 9:3273-3297 (1998) [Exhibit 42];
43. Stetsenko, D.A., et al., "Efficient conjugation of peptides to oligonucleotides by 'native ligation,'" J. Org. Chem. 65:4900-4908 (2000) [Exhibit 43];
44. Sundberg, et al., U.S. Patent No. 5,919,523, filed Oct. 24, 1997 [Exhibit 44];
45. Taton, T.A., et al., "Scanometric DNA array detection with nanoparticle probes," Science 289:1757-1760 (2000) [Exhibit 45];
46. Tung, C.H., et al., "Preparation and Applications of Peptide – Oligonucleotide Conjugates," Bioconjugate Chemistry 11:605-618 (2000) [Exhibit 46];
47. Van Gelder, et al., U.S. Patent No. 5,716,785, filed Apr. 19, 1996 [Exhibit 47];

48. Van Gelder, et al., U.S. Patent No. 5,891,636, filed Sep. 3, 1997 [Exhibit 48];
49. Walker, et al., U.S. Patent No. 5,270,184, filed Nov 19, 1991 [Exhibit 49];
50. Wang, E., et al., "High-fidelity mRNA amplification for gene profiling," Nature Biotechnology 18:457-459 (2000) [Exhibit 50];
51. Weslin, L., et al., "Anchored multiplex amplification on a microelectric chip array," Nature Biotechnology 18:199-204 (2000) [Exhibit 51];
52. Winjhoven, et al., International Patent Application No. WO 98/45474, filed April 6, 1998 [Exhibit 52];
53. Yershov, G., et al., "DNA analysis and diagnostics on oligonucleotide microchips," Proc. Nat. Acad. Sci USA 93:4913-4918 (1996) [Exhibit 53];
54. Ying, S-Y., et al., "Generation of Full-Length cDNA Library from Single Human Prostate Cancer Cells," Biotechniques 27:410-414 (1999) [Exhibit 54];

The fifty-four (54) foregoing references (numbers 1-54) were cited in the specification of the instant application.

A completed Form PTO-1449 listing the 54 above-submitted documents is also attached hereto as Exhibit 55.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office								Atty. Docket No. ENZ-60	Serial No. 09/896,897
INFORMATION DISCLOSURE CITATION (use several sheets if necessary)								RECEIVED	
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JAN 07 2004  
PATENT & TRADEMARK OFFICE

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
		5	6	4	1	6	5	8					
		6	2	0	4	3	2	6		Cook et al			
		5	2	4	1	0	6	0		Engelhardt et al			
		5	4	3	2	0	6	5		Fuller			
		5	6	0	5	6	6	2		Heller et al			
		5	1	4	3	8	5	4		Pirrung et al			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	TRANSLATION YES NO
		WO	0	0	3	2	8	2					
	WO	0	0	3	2	8	2	3		Lohse et al			
	EP	0	6	1	1	8	2	8		Pergolizzi et al			
	WO	9	8	4	5	4	7	4		Winjhoven et al			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Adams, et al., "Complementary DNA sequencing: expressed sequence tags and human genome project," <i>Science</i> 252:1651-1656 (1991)
	Afanassiev, et al., "Preparation of DNA and protein micro arrays on glass slides coated with an agarose film," <i>Nucl. Acids Res.</i> 28:e66 (2000)
	Antopolksky, M., et al., "Solid-phase synthesis of peptide-oligonucleotide conjugates on new solid supports," <i>Helv. Chim Acta</i> 82:2130-2140 (1999)
	Arar, K., et al., "Synthesis of oligonucleotide-peptide conjugates containing a KDEL signal sequence," <i>Tetrahedron Letters</i> 34:8087-8090 (1993)
	Arenkov, P., et al., "Protein Microchips: Use for Immunoassay and Enzymatic Reactions," <i>Analytical Biochemistry</i> 278:123-131 (2000)

EXAMINER	DATE CONSIDERED
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\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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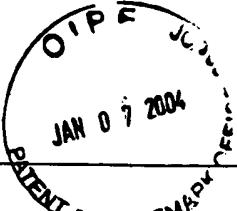
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	0 1 0 4 6 2 0	6/5/03	Rabbani et al			
	0 1 0 4 4 6 0	6/5/03	Rabbani et al			
	5 9 1 9 5 2 3		Sundberg et al			
	5 7 1 6 7 8 5		Van Gelder et al			
	5 8 9 1 6 3 6		Van Gelder et al			

**FOREIGN PATENT DOCUMENTS**

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	Bazin, et al., <i>Innovation and Perspectives in solid Phase Synthesis &amp; Recombinatorial Libraries</i> , R. Epton (Ed.), Mayflower Scientific Ltd., Birmingham, UK (1999)
	Bergmann, F., et al., "Solid phase synthesis of directly linked peptide-oligodeoxynucleotide hybrids using standard synthesis protocols," <i>Tetrahedron Letters</i> 36:1839-1842 (1995)
	Brenner, S., et al., "Encoded Combinatorial Chemistry," <i>Proc. Natl. Acad. Sci. USA</i> 89:5381-5383 (1992)
	Cho, R.J., et al., "A Genome-Wide Transcriptional Analysis of the Mitotic Cell Cycle," <i>Mol. Cell</i> 2:65-73 (1998)
	De La Torre, B.G., et al., "Stepwise solid-phase synthesis of oligonucleotide-peptide hybrids," <i>Tetrahedron Letters</i> 35:2733-2736 (1994)
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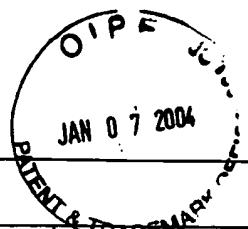
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Gentalen, E., et al., "A novel method for determining linkage between DNA sequences: hybridization to paired probe arrays," <i>Nucleic Acids Research</i> 27:1485-1491 (1999)
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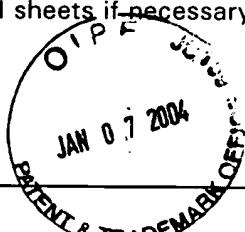
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## FOREIGN PATENT DOCUMENTS

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